UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 8-K

Current Report

Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 15, 2021

BIOCEPT, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-36284**	**80-0943522**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

9955 Mesa Rim Road, San Diego, CA	**92121**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (858) 320-8200

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Securities Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	BIOC	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On November 15, 2021, we issued a press release announcing our financial results for the three and nine months ended September 30, 2021. A copy of the press release and accompanying information is attached as Exhibit 99.1 to this current report.

The information in this Item 2.02, and Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this current report shall not be incorporated by reference into any registration statement or other document filed with the Securities and Exchange Commission, whether filed before or after the date hereof regardless of any general incorporation language in any such filing, unless we expressly set forth in such filing that such information is to be considered "filed" or incorporated by reference therein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release dated November 15, 2021.
104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Biocept, Inc.

Date: November 15, 2021

By: /s/ Timothy C. Kennedy
Timothy C. Kennedy
Chief Financial Officer and Chief Operating Officer

EXHIBIT 99.1

Biocept Reports Third Quarter 2021 Financial Results

- *Revenues for the third quarter of $17.5 million, up 165% over prior-year quarter, driven by increased RT-PCR COVID-19 testing, resulting in profitability; cash balance of $27.7 million at quarter-end*
- *Robust CNSide™ sequential-quarter volume growth; continued customer base expansion*
- *Data generated by leading cancer center demonstrates superior performance of CNSide versus standard of care*

Conference call begins at 4:30 p.m. Eastern time today

SAN DIEGO (November 15, 2021) – Biocept, Inc. (Nasdaq: BIOC), a leading provider of molecular diagnostic assays, products and services, reports financial results for the three and nine months ended September 30, 2021 and provides a business update.

"With CNSide, our paradigm-changing neuro-oncology test that uses cerebrospinal fluid for diagnosing and monitoring patients with brain metastases, we are reporting strong sequential quarter volume growth, primarily driven by data generated with our academic partners," said Michael Nall, Biocept's President and CEO. "Our customer base for this proprietary service continues to grow, with the majority as repeat users.

"As an update on our RT-PCR COVID-19 testing services, we have now received more than 660,000 samples for testing since June 2020. Testing volume increased during the third quarter due to the emergence of the Delta variant and our contracted services with the California community college system," he added. "Revenue from COVID-19 testing drove profitability for both the quarter and year-to-date, which in turn supports continued investment in our long-term oncology business."

Third Quarter 2021 and Recent Highlights

Commercial Developments and Agreements

Oncology

- Expanded the customer base for CNSide to 40 top U.S. academic institutions. CNSide is Biocept's cerebrospinal fluid assay that offers a timely and accurate method to diagnose patients with lung and breast cancer that has metastasized to the central nervous system, along with the ability to identify actionable biomarkers and assess a patient's response to therapy.
- Received a positive coverage decision from Medicare and high-value reimbursement of $2,435 for the Target Selector breast cancer assay to detect the HER2 biomarker from circulating tumor cells (CTCs) in liquid biopsy.

COVID-19

- Implemented COVID-19 testing services at more than 30 community college campuses across California, streamlining the testing and tracking process for administrators, and allowing students and staff to easily schedule and fulfill COVID-19 testing requirements.

Scientific Presentations

- Presented new data from a retrospective study conducted by the University of Utah Huntsman Cancer Center in a poster at the Third Annual Conference on Brain Metastases hosted by the Society for Neuro-Oncology. Study data showed CNSide detected tumor cells in 100% of samples from 15 patients with lung cancer and leptomeningeal carcinomatosis, while standard of care CSF cytology detected tumor cells in 40% of samples. CNSide also identified actionable biomarkers for treatment decision-making extending life and quality of life for some patients.
- Co-sponsored webinar with *Cap Today* entitled "A new CSF assay can improve detection and management of brain metastases," featuring presentation by Michael Dugan, MD, Senior Vice President, Chief Medical Officer and Medical Director of Biocept; Seema Nagpal, MD, Clinical Associate Professor of Neurology, Division of Neuro-oncology, Stanford University; and Santosh Kesari, MD, PhD, Professor of Neurosciences, Chair of the Department of Translational Neurosciences, Director of Neuro-Oncology Saint John's Cancer Institute.
- Presented data at the Third Annual RAS-Targeted Drug Development Summit on Target Selector assay formats for the ultra-sensitive detection of KRAS mutations using Switch-Blocker™ technology, which provides advantages for the assessment of therapeutic tumor response and is cost effective for serial monitoring.
- Study results were published in the November 2021 issue of the *Journal of Molecular Diagnostics* showing that the addition of Switch-Blocker technology to common PCR-based liquid biopsy assays increased sensitivity in detecting rare cancer mutations by 200-1,000 times.

Corporate Developments

- Named Samuel Riccitelli as Chairman of the Board; Mr. Riccitelli joined the Biocept Board of Directors in October 2020.
- Expanded Board membership to nine with the appointments of Linda Rubinstein and Antonino Morales as Directors. Ms. Rubenstein and Mr. Morales bring extensive financial and leadership experience to support growth initiatives and advance the company's oncology diagnostics franchise.
- Named David Karlander as Senior Vice President of Commercial Operations with responsibility for all sales, marketing and reimbursement initiatives. He brings to Biocept more than 25 years of experience including building and managing major brands in clinical diagnostics, medical devices and pharmaceuticals through all stages of commercialization.

Intellectual Property

- Awarded a South Korean patent for the Primer-Switch technology, which detects rare mutations in circulating tumor DNA (ctDNA) using RT-PCR and associated analysis methods. Biocept's core technology and products are currently protected by 71 patents worldwide.

Third Quarter Financial Results

Net revenues for the third quarter of 2021 were $17.5 million, an increase of 165% from $6.6 million for the third quarter of 2020, with the increase primarily attributable to higher RT-PCR COVID-19 testing. Revenues for the third quarter of 2021 included $16.5 million in RT-PCR COVID-19 test revenue, $826,000 in oncology test revenue, $34,000 in development services test revenue and $71,000 in revenue for distributed products, Target Selector RUO kits, CEE-Sure® blood collection tubes and payments for development services. Net revenues for the third quarter of 2020 included $5.7 million in RT-PCR COVID-19 test revenue, $713,000 in oncology test revenue, $47,000 in development services test revenue and $154,000 in revenue for distributed products, Target Selector RUO kits and CEE-Sure blood collection tubes and payments for development services.

Biocept accessioned 154,324 total samples and 152,796 commercial billable samples during the third quarter of 2021, compared with 52,542 total samples and 48,109 commercial billable samples during the third quarter of 2020. The increases were primarily attributable to higher COVID-19 testing.

Cost of revenues for the third quarter of 2021 was $10.3 million, compared with $5.9 million for the third quarter of 2020, with the increase primarily due to higher COVID-19-related collection kits and consumable expenses.

Research and development (R&D) expenses for the third quarter of 2021 were $1.3 million, compared with $1.1 million for the third quarter of 2020, with the increase primarily attributable to increases in headcount-related expenses and material costs associated with investment in CNSide clinical development. General and administrative (G&A) expenses for the third quarter of 2021 were $3.4 million, compared with $3.0 million for the third quarter of 2020, with the increase primarily due to headcount additions and other expenses related to COVID-19 volume. Sales and marketing expenses for the third quarter of 2021 were $1.9 million, compared with $1.4 million for the third quarter of 2020, with the increase due to higher COVID-19 revenue and marketing costs related to CNSide.

Net income attributable to common stockholders for the third quarter of 2021 was $427,000, or $0.03 per diluted share on 15.6 million weighted-average shares outstanding. This compares with a net loss attributable to common stockholders for the third quarter of 2020 of $4.9 million, or $0.37 per share on 13.3 million weighted-average shares outstanding.

Nine Month Financial Results

Net revenues for the first nine months of 2021 were $47.3 million, including a $1.1 million increase in reserves for aged accounts receivables recognized in the second quarter of 2021, compared with $9.0 million for the first nine months of 2020. Revenue for the first nine months of 2021 included $47.0 million in commercial test revenue, $107,000 in development services test revenue and $167,000 in revenue for Target Selector RUO kits and CEE-Sure blood collection tubes and payments for development services.

Operating expenses for the first nine months of 2021 were $45.9 million, and included cost of revenues of $26.8 million, R&D expenses of $3.5 million, G&A expenses of $9.8 million and sales and marketing expenses of $5.8 million.

Net income for the first nine months of 2021 was $1.2 million, or $0.08 per diluted share on 14.3 million weighted-average shares outstanding. This compares with a net loss for the first nine months of 2020 of $19.7 million, or $1.74 per share on 11.3 million weighted-average shares outstanding.

Biocept reported cash and cash equivalents as of September 30, 2021 of $27.7 million, compared with $14.4 million as of December 31, 2020. During the third quarter, the Company raised $9.6 million from the sale of common stock under its at-the-market equity offering facility.

Conference Call and Webcast

Biocept will hold a conference call today at 4:30 p.m. Eastern time to discuss these results and answer questions. The conference call can be accessed by dialing (855) 656-0927 for domestic callers, (855) 669-9657 for Canadian callers or (412) 902-4109 for other international callers. A live webcast of the conference call will be available on the investor relations page of the Company's website at http://ir.biocept.com/events.cfm.

A replay of the call will be available for 48 hours following its conclusion and can be accessed by dialing (877) 344-7529 for domestic callers, (855) 669-9658 for Canadian callers or (412) 317-0088 for other international callers. Please use event passcode 10161580. A replay of the webcast will be available for 90 days.

About Biocept

Biocept, Inc. develops and commercializes molecular diagnostic assays that provide physicians with clinically actionable information for treating and monitoring patients diagnosed with a variety of cancers. In addition to its broad portfolio of blood-based liquid biopsy assays, Biocept has developed the CNSide™ cerebrospinal fluid assay that detects cancer that has metastasized to the central nervous system. Biocept's patented Target Selector™ technology captures and quantitatively analyzes CSF tumor cells for tumor-associated molecular markers, using technology first developed for use in blood. Biocept also is leveraging its molecular diagnostic capabilities to offer nationwide COVID-19 RT-PCR testing to support public health efforts during this unprecedented pandemic. For more information, visit www.biocept.com. Follow Biocept on Facebook, LinkedIn and Twitter.

Forward-Looking Statements Disclaimer Statement

This news release contains forward-looking statements that are based upon current expectations or beliefs, as well as a number of assumptions about future events. Although we believe that the expectations reflected in the forward-looking statements and the assumptions upon which they are based are reasonable, we can give no assurance that such expectations and assumptions will prove to be correct. Forward-looking statements are generally identifiable by the use of words like "may," "will," "should," "could," "expect," "anticipate," "estimate," "believe," "intend" or "project," or the negative of these words or other variations on these words or comparable terminology. To the extent that statements in this news release are not strictly historical, including, without limitation, statements regarding the capabilities and performance of our CNSide assay and Target Selector technology, such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The reader is cautioned not to put undue reliance on these forward-looking statements, as these statements are subject to numerous risks and uncertainties, including risks and uncertainties associated with the continually evolving COVID-19 pandemic and the risk that our products and services may not perform as expected. These and other factors are described in greater detail under the "Risk Factors" heading of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, as filed with the Securities and Exchange Commission (SEC) on August 16, 2021, and under the "Risk Factors" heading of our Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, being filed with the SEC today. The effects of such risks and uncertainties could cause actual results to differ materially from the forward-looking statements contained in this news release. We do not plan to update any such forward-looking statements and expressly disclaim any duty to update the information contained in this press release except as required by law. Readers are advised to review our filings with the SEC at http://www.sec.gov/.

Investor Contact:
LHA Investor Relations
Jody Cain
Jcain@lhai.com, (310) 691-7100

Media Contact:
Sampson PR Group
Andrea Sampson
asampson@sampsonprgroup.com, (562) 304-0301

BIOCEPT, INC.
CONDENSED BALANCE SHEETS

	December 31, 2020	September 30, 2021 (unaudited)
ASSETS		
Cash	$ 14,367,942	$ 27,698,334
Accounts receivable, net	14,144,911	15,972,256
Inventories, net	1,929,624	2,898,325
Prepaid expenses and other current assets	2,151,527	686,330
TOTAL CURRENT ASSETS	32,594,004	47,255,245
FIXED ASSETS, NET	2,317,616	2,151,806
LEASE RIGHT-OF-USE ASSETS	12,114,058	12,100,213
OTHER NON-CURRENT ASSETS	425,908	438,776
TOTAL ASSETS	$ 47,451,586	$ 61,946,040
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES, NET	$ 12,494,253	$ 10,403,908
NON-CURRENT LIABILITIES, NET	11,264,911	11,486,448
TOTAL LIABILITIES	23,759,164	21,890,356
SHAREHOLDERS' EQUITY	23,692,422	40,055,684
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 47,451,586	$ 61,946,040

BIOCEPT, INC.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME/(LOSS)

	For the three months ended September 30,		For the nine months ended September 30,	
	2020 (unaudited)	2021 (unaudited)	2020 (unaudited)	2021 (unaudited)
NET REVENUES	$ 6,586,144	$ 17,469,502	$ 8,950,160	$ 47,27
COSTS AND EXPENSES				
Cost of revenues	$ 5,859,370	$ 10,292,299	$ 11,323,668	$ 26,75
Research and development expenses	1,087,741	1,302,893	3,989,133	3,48
General and administrative expenses	3,023,337	3,434,349	6,839,467	9,80
Sales and marketing expenses	1,434,481	1,938,415	4,232,867	5,80
Total costs and expenses	11,404,929	16,967,956	26,385,135	45,85
(LOSS)/INCOME FROM OPERATIONS	(4,818,785)	501,546	(17,434,975)	1,41
WARRANT INDUCEMENT, INTEREST AND OTHER EXPENSE	(59,549)	(74,499)	(2,274,000)	(21
(LOSS)/INCOME BEFORE INCOME TAXES	(4,878,334)	427,047	(19,708,975)	1,19
INCOME TAXES	—	—	—	
NET (LOSS)/INCOME AND COMPREHENSIVE (LOSS)/INCOME	$ (4,878,334)	$ 427,047	$ (19,708,975)	$ 1,19
Deemed dividend related to warrants down round provision	—	—	(2,774)	
NET (LOSS)/INCOME ATTRIBUTABLE TO COMMON SHAREHOLDERS	$ (4,878,334)	$ 427,047	$ (19,711,749)	$ 1,19
NET (LOSS)/INCOME PER SHARE				
- Basic	$ (0.37)	$ 0.03	$ (1.74)	$
- Diluted	$ (0.37)	$ 0.03	$ (1.74)	$
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING				
- Basic	13,333,427	15,384,469	11,324,289	14,08
- Diluted	13,333,427	15,625,409	11,324,289	14,33

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